

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
2 September 2004 (02.09.2004)

PCT

(10) International Publication Number
WO 2004/073537 A2

(51) International Patent Classification⁷: **A61B 18/20**

(21) International Application Number:
PCT/US2004/005174

(22) International Filing Date: 19 February 2004 (19.02.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/448,762 19 February 2003 (19.02.2003) US

(71) Applicant (for all designated States except US): **PALOMAR MEDICAL TECHNOLOGIES, INC.** [US/US]; 82 Cambridge Street, Burlington, MA 01803 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **YAROSLAVSKY, Ilya** [RU/US]; 9214 Avalon Drive, Wilmington, MA 01887 (US). **SMOTRICH, Michael** [US/US]; 62 Sunset Rock Road, Andover, MA 01810 (US). **ALTSHULER, Gregory, B.** [US/US]; 137 Marion Street, Wilmington, MA 01887 (US). **EROFEEV, Andrei, V.** [RU/US]; 38 Royal Crest Drive #7 (US).

(74) Agents: **ENGELLENER, Thomas, J.** et al.; Nutter McClennen & Fish LLP, World Trade Center West, 155 Seaport Boulevard, Boston, MA 02210-2604 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

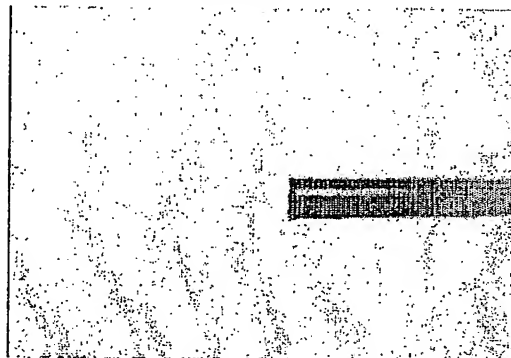
Published:

— without international search report and to be republished upon receipt of that report

[Continued on next page]

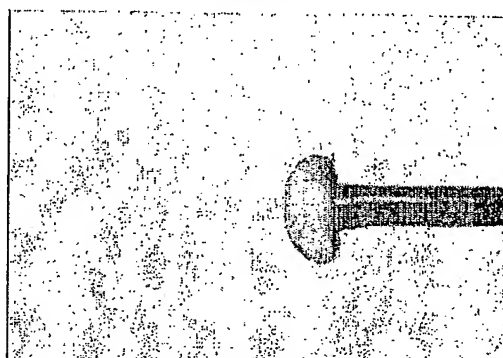
(54) Title: METHOD AND APPARATUS FOR TREATING PSEUDOFOLLICULITIS BARBAE

Before



a

After



b

(57) Abstract: Method and apparatus for hair treatment are disclosed which comprise applying electromagnetic radiation (EMR) to a skin treatment area to deposit energy in one or more hairs so as to modify a shape and/or chemical structure of at least a portion of the hairs. The applied radiation can cause heating of the hair tips, so as to modify their shape, e.g., reduce sharpness of the hair tips. Modification of the hair can involve heat-induced changes to the shape, composition, or function of the hair tip, hair shaft, and/or hair matrix that make the hair less capable of re-entering the skin. The methods and apparatus can treat and/or prevent pseudofolliculitis barbae (PFB) in the treatment area. A method is also disclosed for managing hair growth using wavelengths between 1200 nm and 1400 nm.

WO 2004/073537 A2

WO 2004/073537 A2



For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

- 1 -

METHOD AND APPARATUS FOR TREATING PSEUDOFOLLICULITIS BARBAE

5

PRIORITY

This application claims priority to U.S. provisional application No. 60/448,762 filed February 19, 2003.

BACKGROUND OF THE INVENTION

10

The present invention is generally directed to hair treatment methods, and more particularly, to methods and apparatus for treatment and prevention of pseudofolliculitis barbae (PFB) by utilizing electromagnetic radiation.

15

Pseudofolliculitis barbae (PFB) is a chronic papulopustular dermatitis of a bearded area resulting from reentry penetration of the epidermis by a growing hair. PFB occurs more prevalently in persons (males and females) having curly hair. Persons of darker (IV to VI) skin types are also particularly susceptible to this condition. Epidemiological studies (PK Perry et al. *J. Am. Acad. Dermatol.*, 46:S113-S119, 2002) give estimates of incidence between 45% and 83% for black patients.

20

Pathogenesis of PFB is determined by a person's hair structure. The curved pattern of the hair growth is the principal characteristic that initiates the process. In persons having such a pattern of hair growth, the hair emerges from the skin surface and turns in the direction of the epidermis. The growth continues in a direction as if to complete a full circle (i.e., extrafollicular penetration), resulting in the hair penetrating into the skin. A foreign-body-type inflammatory reaction that follows produces a plurality of papules and, in a continuing spectrum, pustules. Alternatively, the emerging hair penetrates the wall of the follicle rather than arcing across a portion of skin prior to reentry (i.e., transfollicular penetration).

30

- 2 -

Conventional treatment approaches include 1) beard growing; 2) PFB-specific shaving techniques; 3) application of depilatories and topical creams (e.g., U.S. Patent No. 6,352,690); and 4) electrolysis for treatment of ingrown hairs (e.g., U.S. Pat. No. 5,419,344).

Recently, laser-based treatment modalities, initially developed for removal of unwanted hair, have been applied for treatment of PFB. The conventional treatment modalities, however, suffer from a number of short comings. In particular, beard growing is not an option for many occupations and PFB-specific shaving techniques are cumbersome, time-consuming, and often not sufficiently effective. Topical depilatories can be difficult to use and may cause severe skin irritation, exacerbating the condition. Electrolysis can only be performed by a trained professional, is expensive and extremely time-consuming. Laser modalities do offer a curative solution to the problem; however, they are currently only available at medical facilities, and existing systems may be sub-optimal for patients with darker skin types.

Thus, there exists an need in the art for a safe, effective, self-treatment method of PFB.

SUMMARY OF THE INVENTION

In one aspect, the present invention provides a hair treatment method comprising applying electromagnetic radiation (EMR) to a skin treatment area to deposit energy in one or more hair tips in the area so as to modify at least a portion of the hair tips. The applied radiation can cause heating of the hair tips, which can extend, for example, from about 0.2 mm below the skin surface to about 1 mm above the skin surface, so as to modify their shape, e.g., reduce sharpness of the hair tips. Modification of the hair tip can involve heat-induced changes to the shape of the hair tip that make the hair less capable of re-entering the skin (i.e., causing a substantially rounded end of the treated hair tip). Thus, the applied radiation can treat and/or prevent pseudofolliculitis barbae (PFB) in the treatment area. More particularly, modification of the shape of the hair tips can inhibit extrafollicular and/or transfollicular penetration by the hair tips. In some

- 3 -

embodiments, the applied radiation can cause irreversible thermal damage to any of the cortex and/or cuticle of the hair tips.

5 The applied radiation can raise the temperature of the hair tips to a range of about 50 to about 300 °C. Parameters of the radiation may be selected so as to raise the temperature of the hair tips to a range of about 50 to about 300 °C while keeping epidermal temperature in the treatment area below about 65 °C and preferably below 60 °C or 55 °C. A plurality of electromagnetic pulses can be directed to the treatment area
10 so as to apply a fluence in a range of about 0.01 J/cm² to about 1000 J/cm² to the treatment area. The pulses can have pulse widths in a range of about 1 ns to about 5 minute or between about 1 ns to about 1 minute. The pulses can have a repetition rate of 0.1 Hz to about 10 MHz. Typically, the pulses are applied during a treatment session lasting for about 1 ns to about 100 seconds per cm² of the treated area. Preferably, the
15 applied radiation includes wavelength components absorbed by melanin in the hair tips. For example, the radiation can include wavelength components in a range of about 280 nm to about 100,000 nm, and more preferably in a range of about 360 nm to about 600 nm.

20 In a related aspect, the hair treatment method can include cooling the epidermis in the treatment area, for example, to enhance selective heating of the hair tips relative to the epidermis. The cooling step can be performed at any of prior, during or after application of the radiation to the treatment area and may be used to prevent the epidermal temperature in the treatment from increasing to dangerous or uncomfortable
25 levels, i.e., above 100 °C.

 The method of the present invention can further include applying a topical agent to the skin treatment area, where the topical agent can be photoactivated by the radiation to facilitate modifying the shape of the hair tips. The topical agent can include at least
30 one exogenous chromophore, and optionally a vehicle for delivering the exogenous chromophore to the hairs, themselves, or to the pilosebaceous canal of hairs in the treatment area. The exogenous chromophore can be selected to have an absorption

- 4 -

spectrum that at least partially matches the wavelength of the applied radiation so as to facilitate heating of the hair tips.

5 In further aspects, the hair treatment method can include depilating the treatment area. Depilation can be performed by shaving, clipping, applying a depilatory cream, applying additional electromagnetic radiation, or any other suitable technique. For example, the depilating step, which can remove portions of the hair tips protruding above the skin surface, can be performed by applying a plurality of electromagnetic
10 pulses to the treatment area, either before or after applying the treatment pulses of electromagnetic radiation, or substantially simultaneously with applying the treatment pulses of electromagnetic radiation.

 The hair treatment method can also include stretching the skin treatment area
15 before or during treatment. The method may also include lifting the skin treatment area so that the hair tips are more accessible to the applied radiation. The hair tips themselves can be lifted so as to bring them into more direct contact with the applied radiation via any suitable mechanism, such as mechanical, vacuum, or electrostatic mechanisms.

20 In other aspects, the present invention also provides a method of treating hair by applying electromagnetic radiation to a skin treatment area for heating one or more hair shafts in the treatment area to a temperature sufficiently elevated so as to modify the hair shafts. The modification of the hair shafts can cause decreased curling of the hair shafts
25 (i.e., substantial straightening of the hair shafts). The modification may also include increasing the softness of the hair shafts, changing the diameter or shape of the hair, increasing the tensile strength of the hair, and/or increasing the elasticity of the hair. The elevated temperature can be, for example, in a range of about 50 °C to about 300 °C. The radiation can also cause a change in a tensile strength of the hair shafts. The
30 change in the tensile strength can be in a range of about 1 to about 200 MPa of breaking stress. The radiation can provide sufficient modification of the hair shafts (i.e., reduction in the curling of the hair shafts) so as to treat, prevent or reduce pseudofolliculitis barbae (PFB) in the treatment area. The applied electromagnetic

- 5 -

radiation can be delivered to the skin treatment area via a plurality of electromagnetic pulses having wavelength components in a range of about 380 nm to about 2700 nm, preferably about 600 to about 1400 nm, or about 800 to about 1350 nm. Further, the epidermis in the treatment area can be cooled prior to, during and/or after treatment. In addition, hairs in the treatment area can be substantially straightened prior to application of the electromagnetic radiation and/or a topical agent capable of photoactivation by the radiation can be applied to the treatment area to facilitate softening and/or straightening of the hair shafts.

In another aspect, the present invention provides a method of controlling hair growth by applying electromagnetic radiation having wavelength components in a range of about 1200 to about 1400 nm to one or more hair follicles in a skin treatment area so as to modulate hair growth. The applied radiation can cause a deceleration and/or cessation of hair growth. In some embodiments, the applied radiation can cause stimulation of hair growth. For example, the treatment area can be exposed to a plurality of electromagnetic pulses having pulse widths in a range of about 1 ns to about 1 minute to deliver radiation with a fluence in a range of about 0.1 J/cm² to about 1000 J/cm² to the treatment area. The duration and fluence of the applied radiation can be selected so as to cause heating of at least a portion of the hairs to a temperature greater than about 47 °C. Further, the epidermis in the treatment area can be optionally cooled. A topical agent that is capable of photoactivation by the radiation can also be applied to the treatment area to facilitate modulating hair growth.

In yet another aspect, the present invention provides a method of treating hair that includes irradiating a plurality of hair follicles with radiation of a wavelength, and fluence suitable for causing the hair matrix to generate modified hair. The radiation can cause the hair matrix to effect growth of less curly, thinner and/or softer hair by heating the hair bulb, keratogenous zone or bulbar of the hair follicles. The modified hair can exhibit a change in a tensile strength in a range of about 1 to about 200 MPa of breaking stress relative to that of a pre-treatment hair. The thinner hair can exhibit a reduction in diameter in a range of about 1 to about 60 µm relative to that of a pre-treatment hair. The radiation can be delivered to the treatment area via a plurality of electromagnetic

- 6 -

pulses having wavelength components in a range of about 380 nm to about 2700 nm, more preferably about 600 to about 1400 nm and having pulse widths, e.g., in a range of about 1 ns to about 1 minute, so as to expose the treatment area to a fluence in a range of about 0.1 J/cm² to about 1000 J/cm², or more preferably a fluence in a range of about 5 to about 50 J/cm².

In another aspect, the invention provides an apparatus for treating a skin treatment area that includes a radiation source for applying one or more pulses of electromagnetic radiation (EMR) to the skin treatment area to deposit energy in one or more hair tips so as to modify (i.e., change the shape, alter the tensile strength or texture, soften, straighten) at least a portion of the hair tips and a depilating mechanism for depilating at least a portion of the skin treatment area. The depilating mechanism can include implements for shaving, applying a depilatory cream, applying additional electromagnetic radiation, or any hair removing mechanism known in the art. The radiation source can generate electromagnetic pulses having wavelength components in a range of about 300 nm to about 1900 nm. The apparatus can also include a cooling mechanism for cooling epidermis in the treatment area before, during and/or after treatment. The apparatus can also have a sensor for sensing removal of the hair tips protruding above the skin surface and/or a lifting mechanism for enhancing capture of the hair tips by the cutting mechanism. The lifting mechanism can be mechanical and/or electrostatic.

In another aspect, the present invention also provides an apparatus for controlling hair growth, comprising a radiation source for applying electromagnetic radiation having wavelength components in a range of about 1200 to about 1400 nm to one or more hair follicles in a skin treatment area so as to modulate hair growth.

In another embodiment, the invention provides an apparatus for modifying a shape of a least a portion of a hair tip, comprising at least a radiation source generating radiation pulses having wavelengths in a range of about 280 nm to about 100,000 nm and pulse widths in a range of about 1 nsec to about 5 minutes to illuminate a skin treatment area with a fluence in a range of about 0.01 J/cm² to about 1000 J/cm² so as to

- 7 -

modify shapes of at least some hair tips in the treatment area. The invention also provides an apparatus for reducing curliness of hair shafts, comprising one or more radiation sources generating radiation pulses having wavelengths in a range of about 380 nm to about 2700 nm and pulse widths in a range of about 1 nsec to about 1 minute for illuminating a skin treatment area with a fluence in a range of about 0.1 J/cm² to about 1000 J/cm² so as to reduce curliness of at least some hair shafts in the treatment area. In another embodiment, the invention provides an apparatus for controlling hair growth, comprising at least one radiation source generating electromagnetic radiation having wavelength components in a range of about 1200 to about 1400 nm for application to one or more hair follicles in a skin treatment area so as to modulate hair growth, wherein the radiation source can be any of an LED, a laser diode, a filtered arc lamp or a filtered halogen lamp. The apparatuses described in this invention can also include a mechanism for removing portions of the hair tips protruding above the skin surface. In addition, the apparatus can include a positioning mechanism for positioning the hair for treatment. The positioning mechanism can be a mechanical, electrostatic, and/or vacuum source capable of moving a portion of the hair so that the hair can optimally receive the applied radiation.

In another embodiment, the invention provides an apparatus for modifying elasticity of hair shafts comprising one or more radiation sources generating radiation pulses having wavelengths in a range of about 600 to about 1400 nm and pulse widths in a range of about 1 nsec to about 1 minute for illuminating a skin treatment area with a fluence in a range of about 0.1 J/cm² to about 1000 J/cm² so as to modify elasticity of at least some hair shafts in the treatment area.

In yet another embodiment, the invention provides a dermatological system comprising an applicator having a head portion adapted for scanning over a skin treatment area and incorporating at least one radiation source, a tracker coupled to the head portion for generating signals indicative of positions of the head portion during a scan, and a controller coupled to the tracker and the radiation source, the controller periodically activating the radiation source based on position signals received from the tracker. The controller determines a distance traversed by the head portion since a

- 8 -

previous activation of the radiation source based on the position signals. The controller activates the source when the traversed distance exceeds a threshold.

5 BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1A is a picture of a hair tip before EMR treatment;

FIGURE 1B is a picture of the hair tip after EMR treatment;

10 FIGURE 2 is a graph illustrating the results of EMR treatment for skin type VI;

FIGURE 3A is a photograph of a section of a person's leg before treatment;

15 FIGURE 3B is a photograph of the section of a person's leg 3 months after treatment showing changes in the hair shafts;

FIGURE 4 is an absorption spectrum of melanin between 1000 nm and 1400 nm;

20 FIGURE 5 is a graph comparing the change in temperature of the hair tip and the basal layer of skin following irradiation at various wavelengths;

FIGURE 6A is a graph of the transmittance of skin from the skin surface to the hair bulb as a function of wavelength for skin with the waveguide effect in a light hair (1); skin with the waveguide effect in a dark hair (2); and skin without the waveguide effect (3).

25 FIGURE 6B is a graph of the ratio of the temperature raise at the hair matrix to that of the basal layer of the epidermis ("safety ratio") accounting for the waveguide effect as a function of wavelength for light hair (1), and for dark hair (2).

30 FIGURE 7A is a schematic illustration of a "stamping" mode of delivering electromagnetic radiation to a skin treatment area;

- 9 -

FIGURE 7B is a schematic illustration of a “scanning” mode of delivering electromagnetic radiation to a skin treatment area;

5 FIGURE 7C is schematic illustration of a “matrix” mode of delivering electromagnetic radiation to a skin treatment area;

FIGURE 8 is a schematic illustration of one embodiment of the present invention which utilizes a pulsed source of EMR in the scanning mode;

10

FIGURE 9 is a schematic illustration of an embodiment of the present invention in which firing of a new EMR pulse is initiated based on a predefined triggering condition;

15

FIGURE 10 is a schematic illustration of an embodiment of the present invention in which a plurality of EMR sources are organized in a linear array in a handpiece;

FIGURE 11 is a schematic illustration of an embodiment of the present invention in which the EMR sources are positioned in a rotating drum;

20

FIGURE 12 is a schematic illustration of an embodiment of the present invention in which additional implements are included in the apparatus;

FIGURE 13 is a schematic illustration of the experimental set-up used in Example 1;

25

FIGURE 14A is a graph of the temperature profile of hairs in air following EMR treatment at 1060 nm;

FIGURE 14A is a graph of the temperature profile of hairs in air following EMR treatment at 1208 nm; and

30

FIGURE 15 is a graph of the ratio of melanin to water absorption as a function of wavelength.

- 10 -

DETAILED DESCRIPTION OF THE INVENTION

5 The present invention discloses methods of modifying the hair shaft that directly address the cause of PFB, i.e. the hair curliness and the sharp end of the hair resulting from hair plucking and/or shaving. These potential hair shaft modification solutions can advantageously result in a simple inexpensive PFB cure. As disclosed by the present invention, hair shaft modification can be achieved through at least one of the following methods: 1) thermo-induced changes in the structure of the shaft to modify the tensile properties of the hair in such a way that its tendency to curl decreases, 2) thermo-
10 induced shrinkage of the hair shaft to reduce traction between the companion layer and the outer root sheath (ORS), which facilitates shedding of the hair, 3) thermo-induced changes in the companion layer reduce traction between the companion layer and the ORS that, in turn, facilitates shedding of the hair, and 4) thermo-induced changes in the shape (i.e., decreased sharpness) of the hair to decrease the probability of extrafollicular and/or transfollicular penetration.
15

According to aspects of the present invention, PFB can be treated or prevented by applying electromagnetic radiation (EMR) to a plurality of hair follicles or parts thereof in a skin treatment area. A method of treatment of PFB according to the present
20 invention can include a step of examining and identifying portions of skin afflicted with PFB and selectively applying EMR to those regions.

PFB is a skin problem exaggerated by the imposition of environmental and appearance constraints placed on individuals having genetically imposed hair or hair
25 follicles features which on shaving, provide the causal factors of PFB. Furthermore, PFB is not a true folliculitis, in that a pathogenic microorganism is not involved in its etiology. Rather, the basis of its etiology is a foreign-body-type inflammatory response. After close shaving, the sharp edge of the hair shaft transects the wall of the hair follicle or re-enters the epidermis. The present invention describes methods, and apparatus for
30 implementing these methods, that can reduce, prevent and/or treat PFB in a subject.

- 11 -

In one aspect of the invention, electromagnetic radiation (EMR) is applied to a plurality of hair tips such that the shapes of the hair tips are modulated. The term "hair tip" is known in the art, and as used herein generally refers to a portion of the hair that extends from below the skin surface in proximity of the surface to above the skin surface. For example, a hair tip can refer to the portion of the hair shaft extending from a depth of about 0.2 mm below the skin surface to about 1.0 mm above the skin surface. The hair tips are selectively heated to cause temporary or irreversible thermal damage or modification to the cortex and/or cuticle of a hair tip, such that the tip assumes a modified shape. Modification of the hair tip involves heat-induced changes to the shape of the hair tip that make the hair less capable of re-entering. More particularly, the modified shape can be preferably less sharp, e.g., more rounded, than the unmodified hair tip. By way of example, FIGURE 1A and FIGURE 1B provide a comparison, respectively, of a hair tip before a treatment according to the teachings of the invention with a hair tip having a more rounded tip caused by exposure to electromagnetic radiation in accordance with the teachings of the invention, as described in more detail below. The modulation of the hair tip shape can be performed following or simultaneously with depilating the skin treatment area.

In one embodiment, EMR is projected onto the hair tip such that the hair tip reaches a temperature in a range of about 50 °C to about 300 °C. In some embodiments, it is preferable that the temperature of the hair tip exceeds about 100 °C. In other embodiments, it is preferable that the temperature of the hair tip exceeds about 200 °C.

A modification to a hair tip according to this aspect of the invention can be achieved by utilizing EMR having a wavelength longer than about 280 nm. Preferably, the wavelength is in a range of about 280 to about 100,000 nm, more preferably in a range of about 280 to about 1400, and most preferably in the range of about 380 to about 600 nm. Wavelengths absorbed by melanin and/or water in the hair can be targeted for heating.

- 12 -

Heating of hair tips can be achieved selectively so that the underlying skin remains undamaged. This selectivity results from the differences in the heat dissipation characteristics of the hair tips and the skin. While the epidermis also includes areas of melanin, it is mostly in the basal membrane which is located deeper in the skin and has higher thermal contact with surrounded tissue, thereby the EMR is attenuated by the upper layers of the epidermis before reaching the basal membrane and providing substantial heat dissipation relative to the hair tip.

Further, heat from skin tissue (epidermis) can be removed much more efficiently than heat from a hair tip, due to high thermal conductivity of the surrounding tissues. The heat dissipation limits the temperature of the epidermis to below that of the hair tip. In some embodiments, the skin surface may be cleaned before treatment, to remove any thermal conductive material from the tip and/or surrounding areas, thereby enhancing the selective heating of the tip versus skin. In some embodiments, skin surface can be cooled to further ensure heat dissipation from the epidermis. For example, cooled or room-temperature air can be used as a cooling agent. In another aspect, the air flow is used to dry the hair and, thus, decrease the heat flux from the hair tip. In other embodiments, room-temperature or heated air can be supplied to the treatment area before, during, and/or after treatment.

FIGURE 5 is a graph comparing the change in temperature of the hair tip and epidermis following irradiation at various wavelengths. The most effective wavelengths for selective heating of hair tips are in UV and violet spectrum. Typical parameters for this treatment include wavelengths in the range of about 280 to about 100,000 nm, preferably in a range 360-600 nm to limit the penetration of the light into the basal layer of skin, a fluence in a range of about 0.01 J/cm² to 1000 J/cm², and more preferably in a range of about 0.5 to about 50 J/cm². In some embodiments, the electromagnetic energy is applied to the treatment area by exposure of the area to a plurality of electromagnetic pulses having a suitable wavelength, and pulse widths that are preferably shorter than the thermal relaxation time of the hair tip. Thermal relaxation time of the hair tip, which can depend on its diameter and dryness of surrounding medium can be in a range of, e.g., 1 ms to 10 s. Typically, shorter pulse widths are preferable so that this condition is

- 13 -

better fulfilled. The particular pulse width, fluence and wavelength selected for a particular application depends on a number of characteristics, including, but not limited to, skin type and hair color. In some embodiments, the pulse width, fluence and wavelength selected for a given patient will typically deliver less EMR than would be
5 necessary to achieve hair growth reduction or hair removal. Generally, pulse widths in a range of about 1 ns to about 5 minutes are employed.

Various sources of EMR can be used to practice the present invention. Examples
10 include, but are not limited to diode lasers, including quantum-cascade lasers, solid-state lasers, LEDs or other solid-state lightings, an array or matrix of LEDs, arc lamps, halogen lamps, fiber lasers, metal halide lamps, incandescent lamps, RF generators, and microwave generators. The EMR source can produce pulsed or continuous radiation. In general, application of the EMR may be achieved using any suitable apparatus for
15 delivering EMR according to the parameters described above. For example, the device may be structured similarly to a device as described in U.S. Patent No. 6,517,532, U.S. Patent No. 6,508,813, U.S. Patent Application Serial No.: 10/154,756, entitled: "Cooling system for a Photocosmetic Device," filed on May 23, 2002, U.S. Patent Application Serial No.10/702104, filed November 4, 2003 entitled "Methods and Apparatus for
20 Delivering Low Powered Optical Treatments," U.S. Patent Application Serial No. 10/080,652, filed February 22, 2002, entitled "Apparatus and Method for Photocosmetic and Photodermatological Treatment," U.S. Patent Application Serial No. 10/706,721, filed November 12, 2003 entitled "Method and Apparatus for Performing Optical Dermatology," and U.S. Patent No.: 6,514,242 entitled "Method and Apparatus for
25 Laser Removal of Hair."

In some embodiments, EMR is applied perpendicularly to the skin surface or at various angles. For example, it may be appropriate to apply the light obliquely or at a grazing angle, thus facilitating coupling of EMR into hairs growing at an oblique angle
30 to the skin surface.

- 14 -

5 In a preferred embodiment, EMR will be applied after depilating the skin treatment area. The EMR can be applied after each shave or applied as needed (i.e., following every other shave). Depilating may be achieved by using any suitable mechanism for removing at least a portion of the hair tips protruding above the skin. Examples of suitable depilating mechanisms include, but are not limited to, shaving, clipping, applying a depilatory cream, and applying additional electromagnetic radiation. In an preferred embodiment, depilation is achieved through shaving using any suitable apparatus (e.g., a blade or electric razor). Typically, at the time of EMR application, the tip will be located at a depth in a range of 0.2 mm below the skin surface, to 1.0 mm above the surface.

15 In some embodiments, the skin may be stretched prior to treatment such that the hair tips are more accessible to the applied EMR. In other embodiments, a means for mechanical or electrostatic capture of the hair tips can be used in order to bring them into an optimal position for treatment. Alternatively, the EMR can act also as cutting tool, combining clipping and tip processing in a single pass. Air flow, which may be heated, cooled, or at room temperature, can be delivered to the skin treatment area to dry hair tips before EMR exposure.

20 In some embodiments, EMR can be applied at the same time or directly prior to using a straightening implement to align the hair shaft into a straight position after it has been heated and softened by EMR. Such an implement can utilize, for example, mechanical, electrostatic, or chemical action (or combination thereof). Alternatively, a topical substance capable of straightening hair can be applied to the skin treatment area before, during or after EMR treatment. Various hair straighteners are known in the art (See for example, U.S. Patent Nos. 6,537,564 and 6,517,822). Most available hair straighteners are either hydroxide based, with, for example, sodium hydroxide, calcium hydroxide and potassium hydroxide as the active ingredient, or ammonium thioglycolate based.

- 15 -

In some embodiments, topically applied chromophores are employed to facilitate treatment by electromagnetic radiation. The wavelength of EMR can be optimized in order to at least partially match the absorption spectrum of the chromophore. Treatment can also be enhanced by applying the chromophore using a delivery system that provides penetration of the chromophores into the pilosebaceous canal and/or hair shaft. The chromophore may be an organic or non-organic dye in combination with a vehicle. In some embodiments, a topically applied depilatory agent may be applied to facilitate treatment. The depilatory agent may be light or heat activated, such that by concentrating (e.g., focusing) the EMR at the depth of the hair tips, the depilatory agent can be selectively activated in the region of the hair tip. Optionally, the topical composition may contain both the depilatory agent and a chromophore agent for the EMR. The chromophore agent can be selected from the group consisting of dyes, metals, ions, colored particles, photosensitive dyes, photosensitive materials, carbon particles, conductive skin lotions, electrolyte sprays, conductive electrode gels, and oxides. For examples of topical substances, see for example, U.S. Patent No. 6,685,927, U.S. Patent Application Serial No. 10/693682, filed 10/23/03 entitled "Phototreatment Device for Use with Coolants and Topical Substances," which is hereby incorporated by reference in its entirety.

In another aspect of the invention, the hair shaft becomes less curly. "Curly" or "curliness" as used herein refers to a combination of the ability of the hair to form a curved line (loop) and the lack of elasticity of the hair shaft. A decrease in the curliness of the hair can also lead to an increase in the softness of the hair, preferably in the infundibulum area, a modification of the diameter or shape of the hair, an increase in the tensile strength of the hair, and/or an increase in the elasticity of the hair. Thus, the physical and chemical nature of the hair shaft is modified through the application of EMR which heats the hair tips to a temperature in the range of about 50 °C to about 300 °C, preferably greater than 100 °C, and more preferably greater than 200 °C. Typical parameters for this treatment include wavelengths in the range of about 380 to about 2700 nm, preferably in a range of about 600-1400 nm, and more preferably in the range of about 800 – 1350 nm. As a result of the heating, the structure of the tip may change as the material of the tip becomes softer. The terms "soft" or "soften" as used herein are

- 16 -

intended to refer to the thermal induced modification of the structure of the cuticle, cortex or intercellular cement of the hair shaft which decreases the hardness of the edge of the hair tips. Softness can be determined, for example, by measuring the tensile strength of the hair shaft. In some embodiments of the invention, the applied radiation can cause a change in the tensile strength of the hair shafts in a range of about 1 to about 200 MPa of breaking stress, and more preferably in a range of about 5 to about 100 MPa of breaking stress. In some embodiments, the applied radiation may provide not only a change in the physical and chemical properties of the hair shaft resulting in a change in the texture of the hair, but the shape of the hair tip may also be modified as described above.

The hair tips can be selectively heated to cause temporary or irreversible thermal damage or modification to the cortex and/or cuticle of a hair tip. As a result of this treatment, the hair cuticle and/or cortex and/or intercellular cement are modified (i.e., damaged), which can produce less curly hair, softer hair, thinner hair, an increase in the tensile strength of the hair, and/or an increase in the elasticity of the hair. Modification to the cortex and/or cuticle of a hair tip, according to this aspect of the invention, can be achieved using EMR with wavelengths longer than 380 nm. Preferably the wavelength is in a range of about 380 to about 2700 nm, and more preferably in a range of about 600 to about 1400 nm. The wavelength of light may be selected to selectively target lipids, water, melanin, and/or keratin (i.e., components of the hair shaft). Pre-cooling of the epidermis and cooling of the epidermis simultaneously with application of the EMR (known as "parallel" cooling) may also be employed to improve depth selectivity of such treatment. Cooling is more effective on high thermo conductive tissue, such as dermis and epidermis which are significantly more thermoconductive than the hair shaft due to their higher water content. Surface skin cooling is therefore more effective on the dermis than the hair shaft leading to selectivity for hair shaft heating. Selectivity of heating of hair shaft, which has low thermal conductivity, can be achieved by employing wavelengths in the range of about 380 to about 2700 nm.

- 17 -

Typical parameters for this treatment include: a wavelength in the range of about 380 to about 2700 nm, a pulse width of about 1 ns to about 1 minute, and a fluence of about 0.1 to about 1000 J/cm². The pulse width, fluence and wavelength selected for a given patient will typically deliver less EMR than would be necessary to achieve hair growth removal or hair reduction. FIGURE 2 shows exemplary results of this mode of treatment for skin type VI by employing a plurality of radiation pulses having a wavelength of 800 nm, a pulse width of 20 ms, and a fluence of 7.5 J/cm². As a result of this treatment, hair shaft at a depth of about 0 to 0.8 mm has been heated up to 200 °C, while the epidermal temperature does not exceed 65 °C. In some embodiments, the beam width may be selected to be relatively narrow to limit penetration to the depth of the hair shaft. The beam may be shaped as a circle, a line or any other suitable shape so as to limit the penetration using scattering. Some embodiments may utilize focusing the beam so that EMR is concentrated at a desired depth.

In yet another aspect of the invention, a method is provided to modify the hair bulb, keratogenous zone and/or bulbar of a hair follicle, via heating or cooling, to cause a change in the new hair growth. As a result of such heating or cooling, functions of the hair matrix can be affected. In particular, the hair growth process can be modified so as to lead to changes in the nature of the re-growing hair. For example, the newly grown hairs become softer and/or change their shape (reduce cross-section, i.e., become thinner; or increase ellipticity, i.e., become more round), which makes them less susceptible to curling. Also, the chemical structure of the newly grown hair can be modified to make the hair shafts substantially straighter. For selective heating of hair bulb and bulbar, EMR can be applied with wavelengths in the range of about 380 to about 2700, or more preferably in the range of about 600 nm to about 1400 nm, with pulse widths of about 1 ns to about 1 minute, and fluences of about 0.1 J/cm² to about 1000 J/cm², and more preferably in a range of about 1 to about 100 J/cm².

FIGURES 3A and 3B demonstrate the use of the present invention for altering the chemical and physical properties of the hair shafts. An example of hair miniaturization following treatment with EMR is shown through the differences in FIGURE 3A (before treatment) and FIGURE 3B (after treatment). EMR treatment was

- 18 -

applied using a broadband source (wavelengths between 530 and 1200 nm), a fluence of around 12 J/cm² and a pulse width of 20 ms. The pulse width, fluence and wavelength used for a given patient will typically deliver less EMR than would be necessary to achieve hair growth removal or hair reduction for that patient. Selective absorption and/or conductivity and/or thermal property of the bulbar versus surrounded tissue enables selective heating of the bulbar.

In some embodiments, the subcutaneous area can be cooled at the depth of hair bulbar location to a temperature of about 5 °C to about 30 °C so that the hair matrix and/or dermal papilla or/and vascular loop will be selectively affected by EMR treatment. Cooling can be achieved through a variety of mechanisms known in the art such as spraying a cooling substance (i.e., cooled air or liquid), using a phase-change material, or contacting the target area with a cooling element. For example, contact cooling (i.e., by bringing a cooling element in contact with skin surface) can be employed. Alternatively, topical substances can be applied to the skin surface to selectively cool a portion of the treatment region (see, for example, U.S. Patent Application Serial No.: 10/154,756, entitled: "Cooling system for a Photocosmetic Device," filed on May 23, 2002 and U.S. Patent Application Serial No. 10/693682, filed 10/23/03 entitled "Phototreatment Device for Use with Coolants and Topical Substances.")

Further, similar to the above aspects of the invention, a topical agent, e.g., a lotion, can be applied to the skin treatment area to facilitate heating of hair bulb, keratogenous zone and/or bulbar of a hair follicle. The topical agent can include an exogenous chromophore that can penetrate into at least a portion of the hair follicle. The exogenous chromophore can preferably exhibit an absorption spectrum that at least partially matches the wavelength of the applied radiation so as to facilitate heating of the hair shaft.

In yet another aspect, the present invention provides methods for modifying hair growth of a subject. While, the use of EMR for hair removal (see, for example, US Patent 5,595,568) or for reduction of hair growth rate (see for example, WO Patent

- 19 -

Application 2003/077783) is known in the art, the present invention discloses the use of a new range of wavelengths of this purpose. Previous methods and apparatus used optical radiation with wavelength shorter than 1200 nm. However, for darker skin types, treatment with wavelengths shorter than 1200 nm can result in unwanted side effects, such as epidermal damage. To overcome these drawbacks, the present invention recognizes that the wavelength range between about 1200 nm and about 1400 nm can be used to modify hair growth. The pulse width, fluence and/or power can be adjusted so that wavelengths in the range between about 1200 nm and about 1400 nm can be used to slow and/or reduce hair growth, stop hair growth or stimulate hair growth.

FIGURE 4 is an absorption spectrum of melanin between 1000 nm and 1400 nm showing that melanin does absorb light in the near infrared spectrum. Feasibility of using wavelengths longer than 1200 nm for heating melanin-containing targets has been demonstrated in Example 1. Penetration of the optical radiation in the 1200-1400 nm wavelength range to the matrix of the follicle can be facilitated by a waveguide effect in the hair follicle structure. The waveguide effect is caused by a difference in the refractive index between the hair shaft, inner root sheath, out root sheath and surrounding tissue. Specifically, the refractive index of the shaft, inner root sheath, outer root sheath is substantially higher than that of tissue. As a result, light, with a wavelength in a range of about 1200 to 1400 nm coupled to the hair follicle through the infundibulum can propagate down the follicle in a series of total internal reflections (TIRs), which effectively increase the depth of penetration. This effect can be significant in areas of dense hair follicles, such as facial tissue where hair follicle density can be as high as 1000 hairs per cm^2 . In areas of high hair follicle density, i.e., where more than 30% of the skin volume is occupied by hair follicles, use of a large beam results in a waveguide effect that helps propagate light through the bundle of hair follicle waveguides which can diffuse propagation through dermis. For coherent laser beam this structure can play a role similar to a photonics crystal with amplification of waveguide effect on certain wavelengths.

- 20 -

FIGURES 6A and 6B illustrate the impact of this waveguide effect on the amount of optical energy transmitted to the hair bulb. FIGURE 6A is a graph of the transmittance of EMR in the skin from the surface to the location of the hair bulb (of a single follicle) as a function of wavelength for two cases: accounting for the waveguide effect (1) and neglecting the waveguide effect (2).

FIGURE 6B is a graph of the ratio of the transmittance of skin with the waveguide effect to that of the skin without the waveguide effect as a function of wavelength. FIGURE 6B shows that the waveguide effect is most pronounced and particularly advantageous as the wavelength of the applied radiation increases, e.g., longer than 1200 nm. Thus, substantial retardation of hair growth with the wavelengths between 1200 nm and 1400 nm can be achieved using fluences between about 1 J/cm² and 500 J/cm² and pulse widths between about 1 ns and 10 min.

The invention also provides apparatus for depilating and applying EMR to a skin treatment area as discussed below. In some embodiments, the depilating apparatus and the EMR delivery apparatus are located on a single device, such that in a single stroke the EMR is applied subsequent to or substantially simultaneous with depilation. The depilating apparatus may comprise any suitable device for hair removal known in the art, such as a mechanisms for shaving (i.e., a blade or an electrical razor), a mechanism for tweezing hairs (i.e., a rolling device that tweezes hairs as it passes over the skin treatment area), an applicator of depilatory cream, electrolysis, or an applicator of additional electromagnetic radiation. In a preferred embodiment, the EMR can act also as cutting tool, combining clipping and tip processing in a single pass. The apparatus can also contain mechanisms for mechanical or electrostatic capture of the hair tips in order to bring them into an optimal position for treatment. In yet other embodiments of the present invention, the apparatus can contain an air flow mechanism to deliver air to dry the hair tips before EMR exposure and/or a stretching mechanism to stretch the skin treatment area prior to EMR treatment.

A variety of different designs can be adopted for an implementing apparatus for practicing the methods of the invention as described above. In particular, electromagnetic radiation can be applied to a skin treatment area in many different ways in various embodiments for practicing the methods of the invention. By way of example, FIGURES 7A, 7B, and 7C schematically present three exemplary modes of delivering electromagnetic radiation to a skin treatment area. With reference to FIGURE 7A, in a “stamping” mode, an applicator (handpiece) 71 incorporating one or more sources of electromagnetic radiation can be placed on a selected area of skin 72, and a pulse of electromagnetic radiation 73 can be applied to the tissue in this area. The handpiece can then be moved to another portion of the treatment area to apply an EMR pulse to that portion. This process can be repeated until electromagnetic pulses are applied to the entire treatment area.

FIGURE 7B schematically illustrates another mode of applying electromagnetic radiation to a treatment area, herein referred to as “scanning” mode, in which a handpiece incorporating one or more electromagnetic sources is continuously moved along the skin surface to apply electromagnetic energy to the tissue in the treatment area. In many embodiments, a continuous wave (CW) source of electromagnetic energy can be utilized in the scanning mode. In other embodiments, a pulsed source of electromagnetic energy can be employed in the scanning mode, as described in more detail below.

FIGURE 7C schematically illustrates a “matrix” mode of applying electromagnetic radiation to a treatment area. More particularly, a device 76 according to one embodiment of the invention includes a composite EMR source 77 formed as an array of individually addressable EMR sources, such as LEDs, which can be activated simultaneously, sequentially, or in a selected pattern. A treatment area, e.g., a large treatment area such as a whole face, can be positioned near or in contact with a panel 75 of the device 76 to receive radiation from the array of the EMR sources. Further, a beam shaping and/or cooling implement 78 can be optionally employed to optimize the delivery of the electromagnetic radiation to the treatment area.

In some embodiments, it may be advantageous to utilize a pulsed source of EMR in the scanning mode. As shown schematically in FIGURE 8, such an embodiment can employ a system that includes a pulsed source 84, a tracking device 85, and a triggering device 86, e.g., a computer. The system further includes a handpiece (applicator) 81 that delivers electromagnetic radiation to a treatment area 82. The pulsed source may or may not be integrated with the handpiece. In the latter case, radiation is delivered to the handpiece through an additional energy guide 87. The applicator can be equipped with a handle 83 for manual scanning. Alternatively, mechanical scanning can be used. A treatment session can be initiated by placing the applicator on the skin surface and firing the first pulse 88. Then the applicator is moved continuously along the skin surface, scanning the intended treatment area. The tracking device 85 continuously monitors position of the applicator and sends the data to the triggering device 86. Both devices may or may not be integrated with the handpiece and/or with each other.

As shown schematically in FIGURE 9, the triggering device compares the current position 92 of the handpiece with the last firing position 91 to initiate firing of a new pulse based on a predefined triggering condition. In one preferred embodiment, the triggering device selects a reference point (RP) on the applicator's frame, marks its position before the first pulse, and monitors the distance d_r between the current (constantly changing due to scanning) position 94 of RP and its last firing position 93. For example, the triggering device can monitor the following condition:

$$d_r \geq l_h - l_o = l_h(1 - \alpha), \quad (1)$$

where $\alpha = l_o/l_h$ is the desired degree of overlap, l_o is the length of overlap [mm], and l_h is the length of the handpiece's working area [mm]. Once the condition of Eq.(1) is fulfilled, the triggering device can issue a new firing command to the pulsed source. The procedure is repeated until the whole treatment area is covered. The firing command can be in the form of an analogue or digital pulse (or sequence of pulses) and can be transmitted to the pulsed source by a variety of mechanisms (for example, electrical, mechanical, or optical). Other triggering algorithms can be devised by those having ordinary skill in the art without departing from the scope of the present invention.

- 23 -

The tracking device 85 can be implemented by utilizing various techniques. For example, in one embodiment, the tracking device can include a set of wheels and a reading module, which reads angular positions of the wheels. Once the number of rotations corresponding to the Eq.(1) is made, a firing command is issued. In some preferred embodiments, in which the tracking device is a non-contact optical device, the skin surface can be illuminated, and a picture of a limited area can be taken with sufficient frequency (for example, 2 kHz). The sequence of pictures can then be processed, and the differences between the frames can be analyzed in such a way as to determine the shift between the camera positions at the instances when the frames were taken. As a result, position of RP can be reliably monitored. In some preferred embodiments, the tracking device can be a commercially available optical mouse (possibly modified to accommodate for the specific configuration of the application). The tracking device can also perform function of the contact sensor.

The triggering device 86 can be mechanical, electro-mechanical, electrical, electronic, optical or of any other suitable design. It can be either analogue or digital. In some preferred embodiments, the triggering device is an electronic digital device.

Some embodiments can employ composite EMR sources for delivering radiation to a selected skin treatment area, for example, via a stamping or a scanning mode. By way of example, with reference to FIGURE 10, a plurality of EMR sources 101 can be organized in a linear array in a handpiece 102. When handpiece 102 is scanned along the skin surface, a timing device 103 can send firing pulses to the sources 101 according to a programmed sequence to activate all or selected ones of the EMR sources. In this manner, a desired effect on the target can be achieved due to cumulative action of the multiple pulses from the composite source. The firing sequence can also be modified "on the fly" as a function of, for example, scanning velocity or skin conditions (such as pigmentation or erythema), monitored by a tracking device 104. In some embodiments, the apparatus can also have a positioning mechanism 105 for positioning the hair for treatment. The positioning mechanism can be a mechanical, electrostatic, and/or vacuum source capable of moving a portion of the hair so that the hair can optimally receive the applied radiation.

- 24 -

Alternatively, as shown in FIGURE 11, the EMR sources 111 can be positioned in a rotating drum 112. The timing device 113 can generate a firing sequence in such a way as to fire each source in the time instant when the source occupies the “bottom” position 114, facing a portion of the treatment area. Beam-shaping and/or cooling implement 115 can be integrated within the handpiece housing. Other arrangements of sources in an array can be devised by those skilled in the art.

Some embodiments of an apparatus according to the teachings of the invention can include additional implements to further increase efficacy and/or safety of the treatment. For example, with reference to FIGURE 12, the apparatus can include a topical-composition-dispensing implement 121, cooling implement 122, feedback (skin condition monitor) implement 123, or hair straightening implement 124. In addition, the apparatus can include implements, such as, razors, for depilating the treatment area.

In some embodiments, a single apparatus can be utilized for performing two or more treatment methods according to the teachings of the invention.

Example that follows provides further understanding of some aspects of the hair treatment methods according to the teachings of the invention.

Example 1. Comparison of the efficacy of 1064 nm wavelength vs 1208 nm wavelength for heating melanin-containing target (hair)

An experimental set-up shown schematically in FIGURE 13 was employed to compare the efficiency of utilizing a 1208 nm radiation source relative to a 1060 nm source for heating low-melanin-content (“white”) and high-melanin-content (“black”) hairs.

A CW Raman fiber laser 131 was employed to generate radiation at 1060 nm and 1208 nm wavelengths. A 2-mm aperture 136 was utilized to select a portion of a radiation beam 134 having a maximum intensity (“flat top”). A black hair 132 and a white hair 133, which were harvested immediately before performing measurements to

- 25 -

avoid de-hydration, were mounted in the beam path as symmetrically as possible relative to the beam's central point. Total incident power was matched for the two wavelengths at 240 mW (i.e., 7.6 W/cm^2 irradiance). An electronic shutter 135, controlled by a pulse generator, was utilized to generate ~200-ms pulses at both wavelengths (resulting in ~1.5 J/cm² fluence). An infrared thermal camera 137, controlled by a computer 138, was focused at the plane containing the hairs, and points of maximal temperature rise were selected at both hairs. Temporal profiles of the temperature at these points were recorded.

Results:

FIGURES 14A and 14B present, respectively, two temperature histories for each wavelength. Further, Table 1 below summarizes averaged temperature data for both hairs at the two wavelengths.

Table 1.

Wavelength, nm	Maximal temperature rise, °C		Contrast Black/White
	White hair	Black hair	
1060	4.8	21.8	4.5
1208	3.3	11.8	3.6
Ratio 1060/1208	1.5	1.8	1.25

The contrast in temperature rise between the black and the white hairs does not change significantly between the two wavelengths, thus suggesting that melanin remains the dominant absorber at 1208 nm. If it were not so, the change in contrast would be closer to the change in the ratio of melanin/water absorption, shown in FIGURE 15.

The ratio of the temperature rise at 1060 nm to that at 1208 nm is consistent with the melanin absorption spectrum in the IR (See FIGURE 4). The data further indicates that absorption of melanin at 1208 nm appears to be still sufficient to induce substantial efficiency of heating (~8 deg C/(J/cm²) in the present set-up).

- 26 -

Those skilled in the art will appreciate, or be able to ascertain using no more than routine experimentation, further features and advantages of the invention based on the
5 above-described embodiments. Accordingly, the invention is not to be limited by what has been particularly shown and described, except as indicated by the appended claims. All publications and references are herein expressly incorporated by reference in their entirety.

10

- 27 -

CLAIMS:

1. An apparatus for modifying a shape of a least a portion of a hair tip, comprising
5 at least a radiation source generating radiation pulses having wavelengths in a range of about 280 nm to about 100,000 nm and pulse widths in a range of about 1 nsec to about 5 minutes to illuminate a skin treatment area with a fluence in a range of about 0.01 J/cm² to about 1000 J/cm² so as to modify shapes of at least some hair tips in the treatment area.
- 10 2. The apparatus of claim 1, further comprising a mechanism for removing portions of the hair tips protruding above the skin surface.
3. An apparatus for reducing curliness of hair shafts, comprising
15 one or more radiation sources generating radiation pulses having wavelengths in a range of about 380 nm to about 2700 nm and pulse widths in a range of about 1 nsec to about 1 minute for illuminating a skin treatment area with a fluence in a range of about 0.1 J/cm² to about 1000 J/cm² so as to reduce curliness of at least some hair shafts in the treatment area.
- 20 4. The apparatus of claim 3, further comprising a mechanism for removing portions of the hair tips protruding above the skin surface.
5. An apparatus for controlling hair growth, comprising
25 at least one radiation source generating electromagnetic radiation having wavelength components in a range of about 1200 to about 1400 nm for application to one or more hair follicles in a skin treatment area so as to modulate hair growth,
wherein said radiation source can be any of an LED, a laser diode, a filtered arc lamp or a filtered halogen lamp.
- 30

- 28 -

6. An apparatus for modifying elasticity of hair shafts, comprising
one or more radiation sources generating radiation pulses having wavelengths in
a range of about 600 to about 1400 nm and pulse widths in a range of about 1 nsec to
about 1 minute for illuminating a skin treatment area with a fluence in a range of about
0.1 J/cm² to about 1000 J/cm² so as to modify elasticity of at least some hair shafts in
the treatment area.
7. A dermatological system, comprising
an applicator having a head portion adapted for scanning over a skin treatment
area and incorporating at least one radiation source,
a tracker coupled to said head portion for generating signals indicative of
positions of said head portion during a scan, and
a controller coupled to said tracker and said radiation source, said controller
periodically activating said radiation source based on position signals received from the
tracker.
8. The apparatus of claim 7, wherein said controller determines a distance traversed
by said head portion since a previous activation of said radiation source based on said
position signals.
9. The apparatus of claim 8, wherein said controller activates the source when said
traversed distance exceeds a threshold.
10. A hair treatment method comprising:
applying electromagnetic radiation (EMR) to a skin treatment area to deposit
energy in one or more hair tips in the area so as to modify a shape of at least a portion of
said hair tips.
11. The method of claim 10, wherein said step of applying radiation comprises
exposing at least a portion of said treatment area to a plurality of EMR pulses.

- 29 -

12. The method of claim 10, wherein said applied radiation causes heating of said hair tips so as to reduce sharpness of said tips.

5 13. The method of claim 10, wherein said applied radiation modifies the shape of said hair tips to a substantially rounded shape.

14. The method of claim 10, wherein said applied radiation modifies the shape of said hair tips so as to inhibit extrafollicular and/or transfollicular penetration of said hair tips.
10

15. The method of claim 10, wherein said applied radiation causes any of treatment and/or prevention of pseudofolliculitis barbae (PFB) in the treatment area.

15 16. The method of claim 10, wherein said applied radiation raises temperature of said hair tips to a range of about 50 to about 300 °C.

17. The method of claim 10, further comprising selecting said applied radiation so as to raise temperature of said hair tips to a range of about 50 to about 300 °C while keeping epidermal temperature in the treatment area below about 65 °C.
20

18. The method of claim 11, wherein said pulses have pulse widths in a range of about 1 ns to about 5 minute.

25 19. The method of claim 11, wherein said pulses have pulse widths between about 1 microsecond to about 100 milliseconds.

20. The method of claim 19, wherein said pulses have a repetition rate ranging from about 0.1 Hz to about 1 MHz.

30 21. The method of claim 10, wherein said radiation applies a fluence in a range of about 0.01 J/cm² to about 1000 J/cm² to said treatment area.

- 30 -

22. The method of claim 10, wherein said applied radiation includes wavelength components in a range of about 280 nm to about 100000 nm.
- 5 23. The method of claim 10, wherein said applied radiation includes wavelength components in a range of about 380 nm to about 600 nm.
24. The method of claim 10, wherein said applied radiation includes wavelength components absorbed by at least one of melanin, water, and keratin in said hair tips.
- 10 25. The method of claim 10, further comprising drying hair tips in the treatment area prior to said application of the electromagnetic radiation.
26. The method of claim 25, further comprising delivering a flow of air over said treatment area to dry said hair tips.
- 15 27. The method of claim 10, further comprising the step of cooling the epidermis in the treatment area.
- 20 28. The method of claim 27, wherein said cooling step is performed at any of prior, during or after application of said radiation to the treatment area.
29. The method of claim 10, further comprising applying a topical agent to said skin treatment area, said topical agent being photoactivated chemically or thermally by said radiation to facilitate modifying the shape of the hair tips.
- 25 30. The method of claim 29, wherein said topical agent comprises at least one chromophore.
- 30 31. The method of claim 30, wherein said topical agent comprises a vehicle for delivering said chromophore to the pilosebaceous canal of hairs in said treatment area.

- 31 -

32. The method of claim 10, wherein said hair tips extend from about 0.2 mm below the skin surface to about 1 mm above the skin surface.

5 33. The method of claim 10, further comprises removing portions of hair tips protruding above the skin surface prior to applying said radiation.

34. The method of claim 33, wherein said step of removing portions of hair tips is performed substantially simultaneously with applying said electromagnetic radiation.

10

35. The method of claim 33, wherein the step of removing portions of the hair tips is selected from the group consisting of shaving, clipping, applying a depilatory cream, or applying additional electromagnetic radiation.

15

36. The method of claim 10, wherein the method further comprises stretching the skin treatment area.

37. The method of claim 10, wherein the method further comprises lifting hairs in the skin treatment area.

20

38. A method of treating hair, comprising
applying electromagnetic radiation to a skin treatment area for one or more hair shafts in the treatment area so as to cause a change in elasticity of said hair shafts.

25

39. The method of claim 38, wherein said radiation increases elasticity of said irradiated hair shafts.

40. The method of claim 38, wherein said radiation causes a change in a tensile strength of said hair shafts in a range of about 1 to about 200 MPa of breaking stress.

30

41. The method of claim 38, wherein said radiation causes substantial straightening of said hair shafts.

- 32 -

42. The method of claim 38, wherein said elasticity change of said hair shafts facilitates any of prevention or treatment of pseudofolliculitis barbae (PFB) in the treatment area.

5

43. The method of claim 38, wherein said elevated temperature is in a range of about 50 °C to about 300 °C.

10

44. The method of claim 38, wherein said step of applying electromagnetic radiation comprises applying a plurality of electromagnetic pulses to said treatment area.

45. The method of claim 44, wherein said radiation includes wavelength components in a range of about 380 nm to about 2700 nm.

15

46. The method of claim 44, wherein said radiation includes wavelength components in a range of about 600 nm to about 1400 nm.

47. The method of claim 44, wherein said pulses have pulse widths in a range of about 1 nsec to about 1 minute.

20

48. The method of claim 47, wherein said pulses provide a fluence in a range of about 0.1 J/cm² to about 1000 J/cm².

49. The method of claim 44, further comprising cooling the epidermis in said treatment area.

25

50. The method of claim 44, further comprising applying a topical agent to said treatment area, said topical agent being capable of photoactivation by said radiation to facilitate softening of the hair shafts.

30

- 33 -

51. A method of controlling hair growth, comprising
applying electromagnetic radiation having wavelength components in a range of
about 1200 to about 1400 nm to one or more hair follicles in a skin treatment area so as
5 to modulate hair growth.
52. The method of claim 51, wherein said applied radiation causes a deceleration of
hair growth.
- 10 53. The method of claim 51, wherein said applied radiation causes a cessation of hair
growth.
54. The method of claim 51, wherein said applied radiation causes a stimulation of
hair growth.
- 15 55. The method of claim 51, wherein said modulation of hair growth causes any of
prevention or treatment of pseudofolliculitis barbae (PFB) in the treatment area.
56. The method of claim 51, further comprising selecting a fluence of said applied
20 radiation to be in a range of about 0.1 J/cm² to about 1000 J/cm².
57. The method of claim 51, wherein the step of applying radiation comprises
exposing the skin treatment area to a plurality of radiation pulses having pulse widths in
a range of about 1ns to about 1000s.
- 25 58. The method of claim 51, further comprising the step of cooling the epidermis in
the treatment area.
59. The method of claim 51, further comprising selecting duration and fluence of
30 said applied radiation so as to cause heating of at least a portion of said hair follicles.

- 34 -

- 5 60. A method of treating hair, comprising
irradiating a plurality of hair follicles in a treatment area with radiation of a
wavelength, and fluence suitable for decreasing curliness of at least a portion of said
hairs.
- 10 61. The method of claim 60, wherein said irradiated portion of the hair follicles
comprises at least one of the hair bulb, keratogenous zone and bulbar of the hair
follicles.
62. The method of claim 60, wherein said radiation causes the hair matrix to effect
growth of thinner hair.
- 15 63. The method of claim 60, wherein said hair having reduced curliness exhibits a
change in a tensile strength in a range of about 1 to about 200 MPa of breaking stress
relative to that of a pre-treatment hair.
- 20 64. The method of claim 60, wherein said hair having reduced curliness exhibits a
reduction in diameter in a range of about 1 to about 60 micrometers relative to that of a
pre-treatment hair.
65. The method of claim 60, further comprising selecting said wavelength to be in a
range of about 380 nm to about 2700 nm.
- 25 66. The method of claim 60, further comprising selecting said wavelength to be in a
range of about 600 nm to about 1400 nm.
- 30 67. The method of claim 60, further comprising selecting said fluence to be in a
range of about 0.1 J/cm² to about 1000 J/cm².
68. The method of claim 60, wherein said irradiating step comprises applying a
plurality of electromagnetic pulses to said treatment area.

- 35 -

69. The method of claim 60, wherein said pulses have pulse widths in a range of about 1 ns to about 10 minute.

5

1 / 15

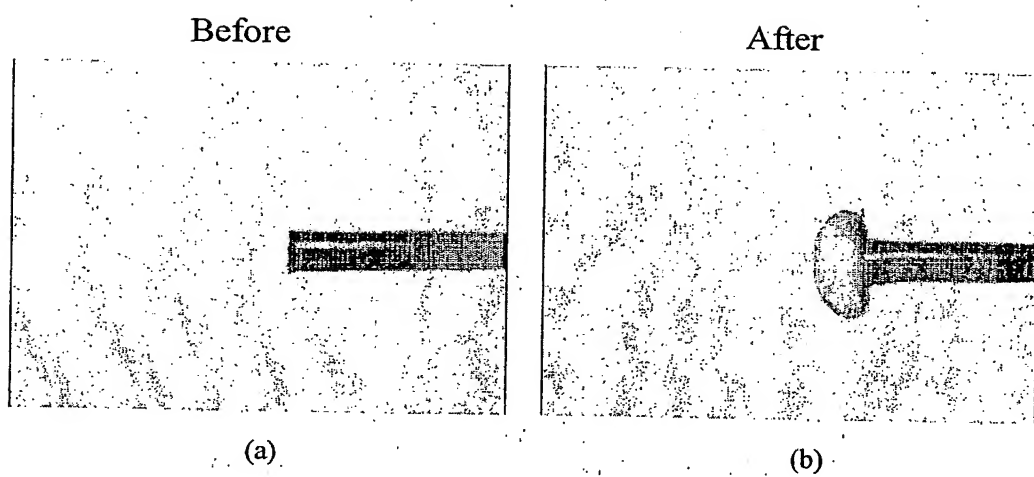


FIGURE 1

2 / 15

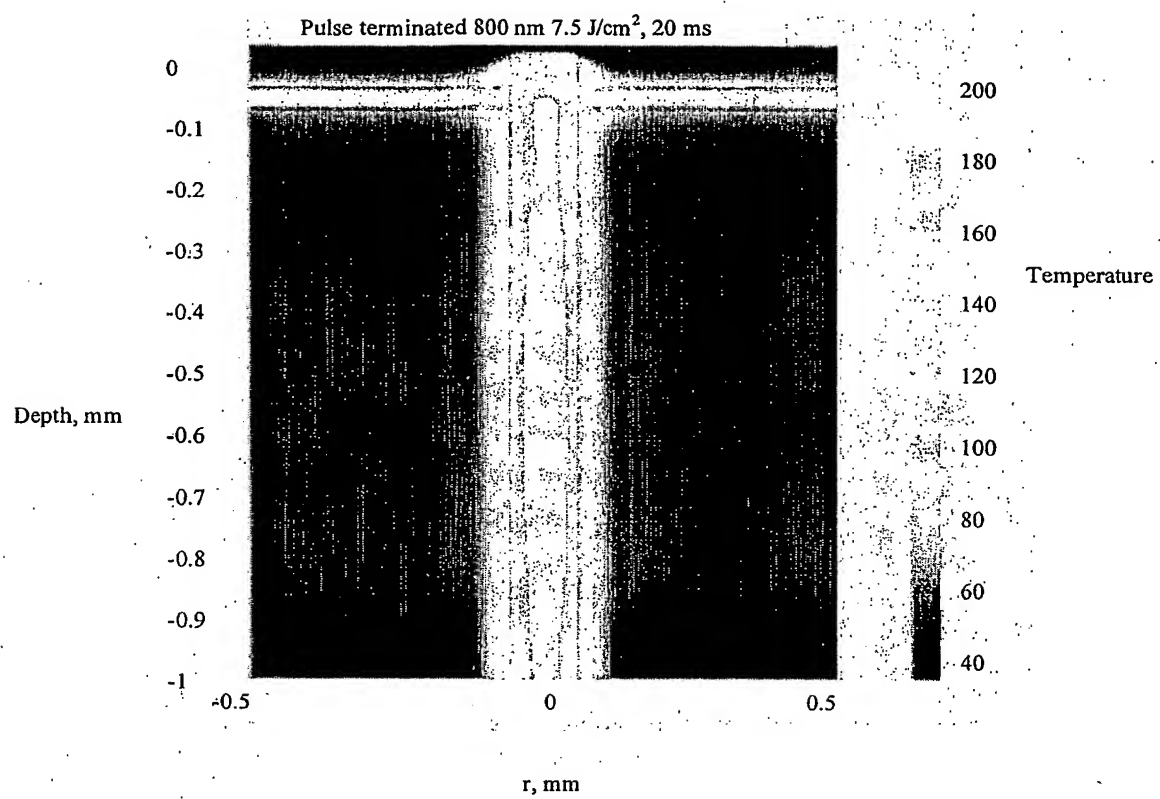
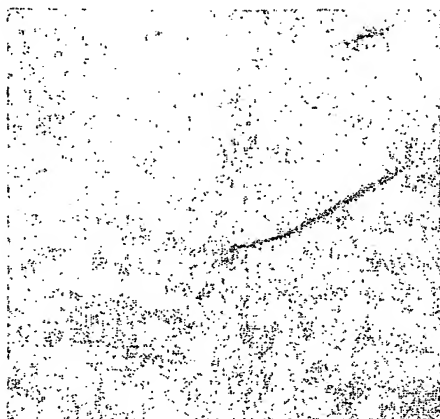


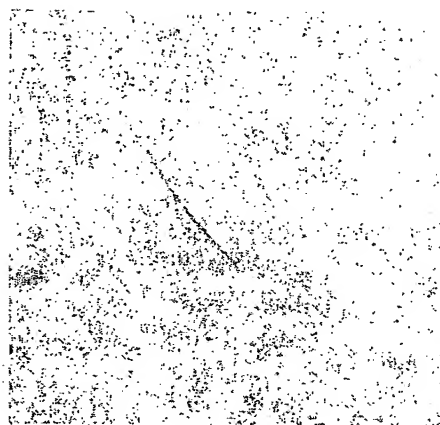
Figure 2

3 / 15



2 weeks after shaving

a

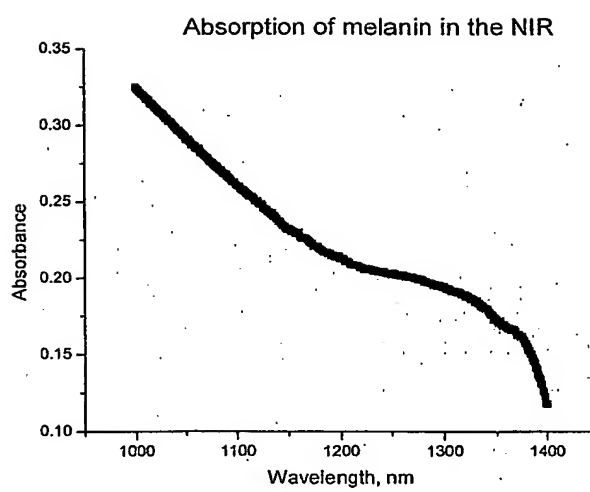


2 weeks after shaving and lasing

b

Figure 3

4 / 15

**Figure 4**

5 / 15

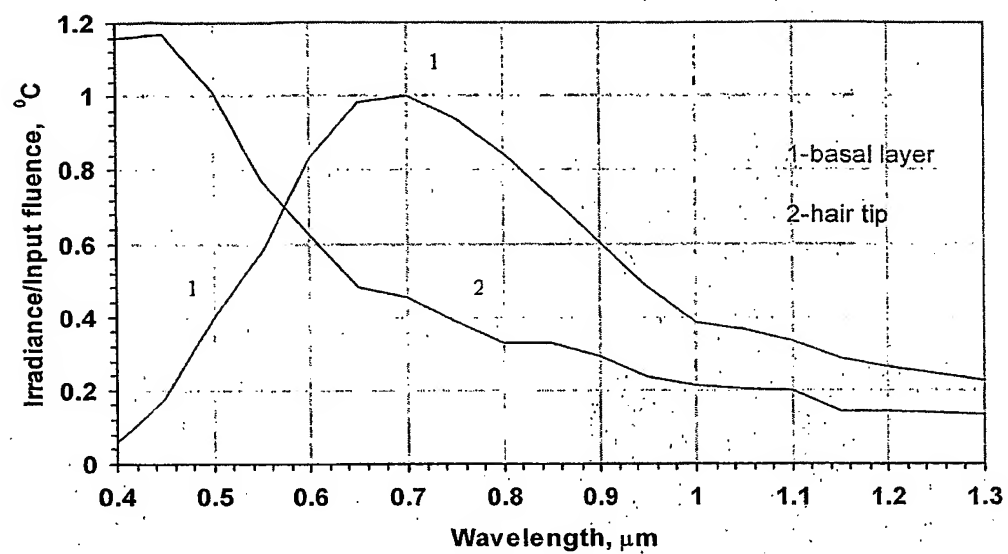
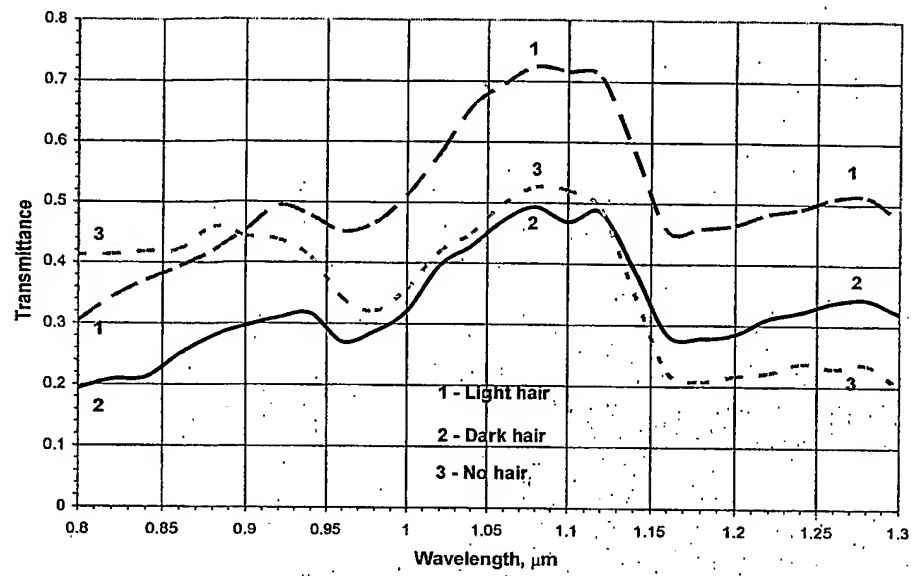
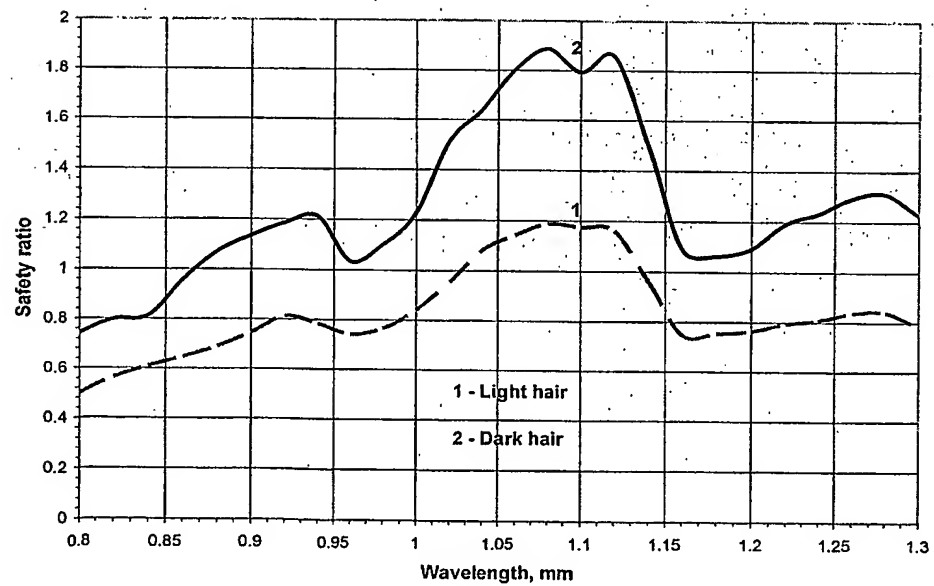


Figure 5

6 / 15



(a)



(b)

Figure 6

7 / 15

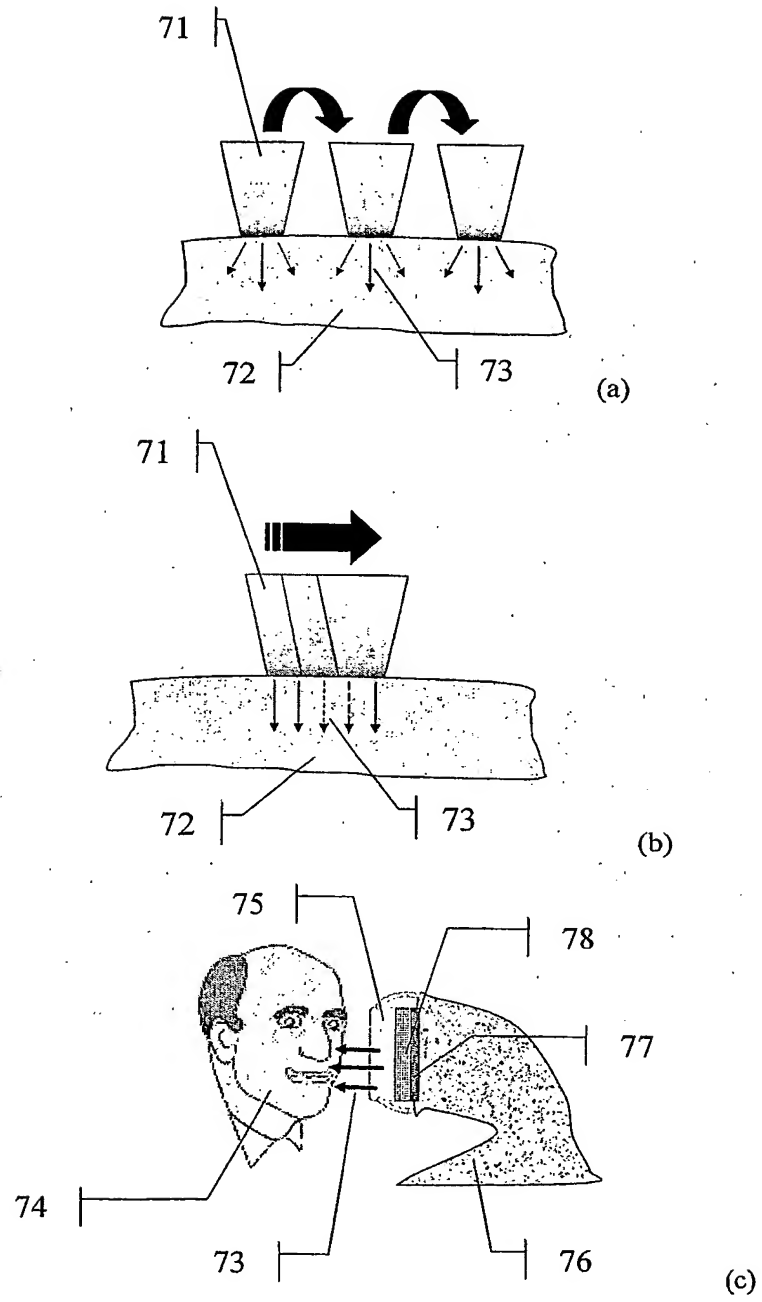


Figure 7

8 / 15

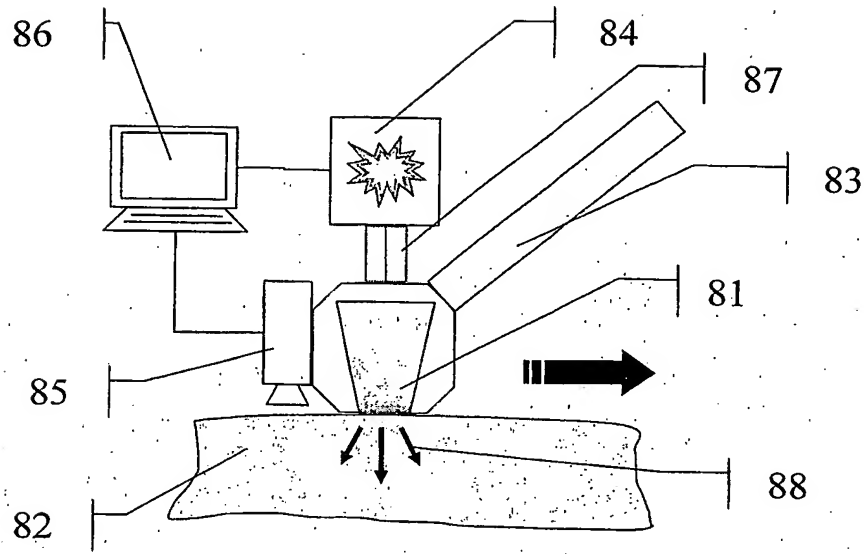


Figure 8

9 / 15

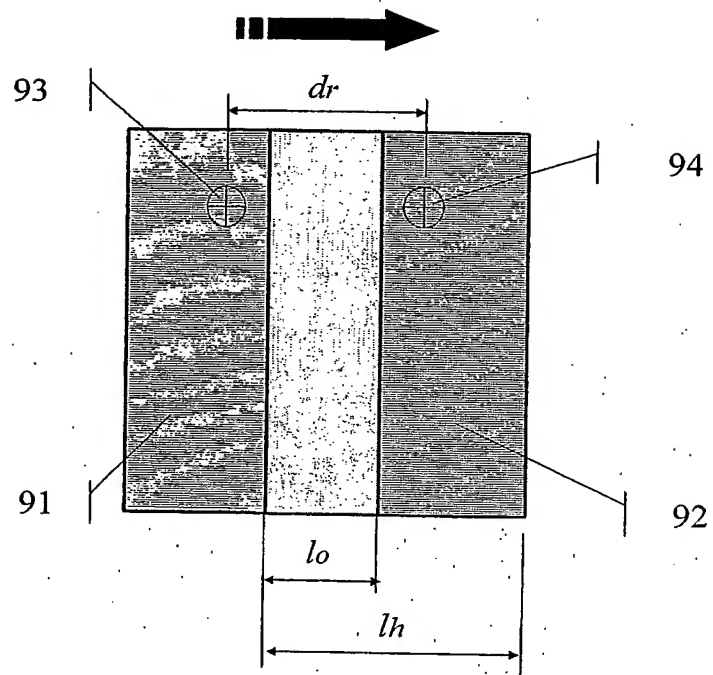


Figure 9

10 / 15

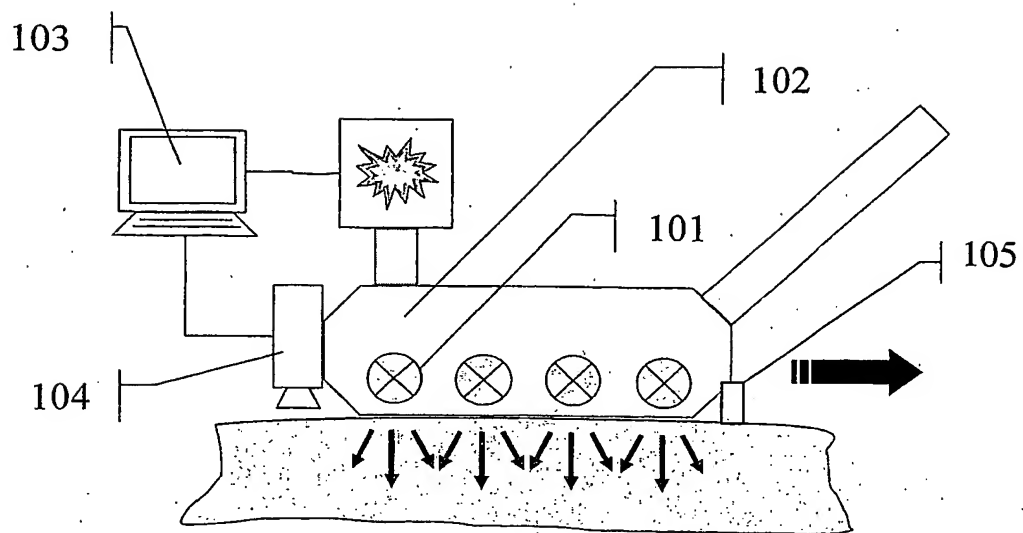


Figure 10

11 / 15

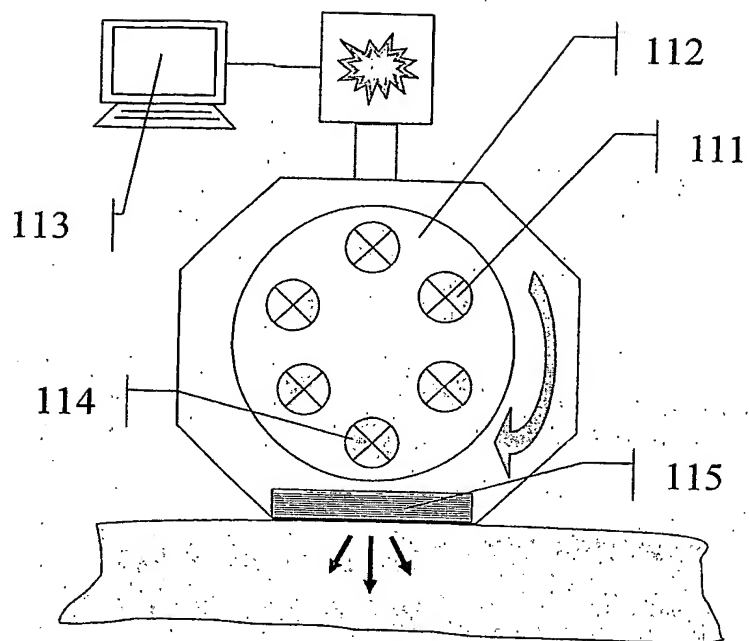


Figure 11

12 / 15

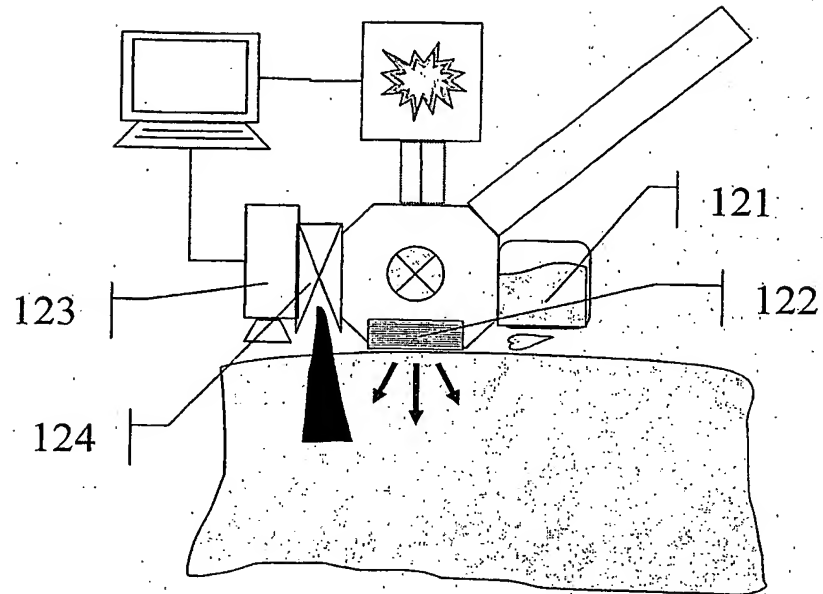


Figure 12

13 / 15

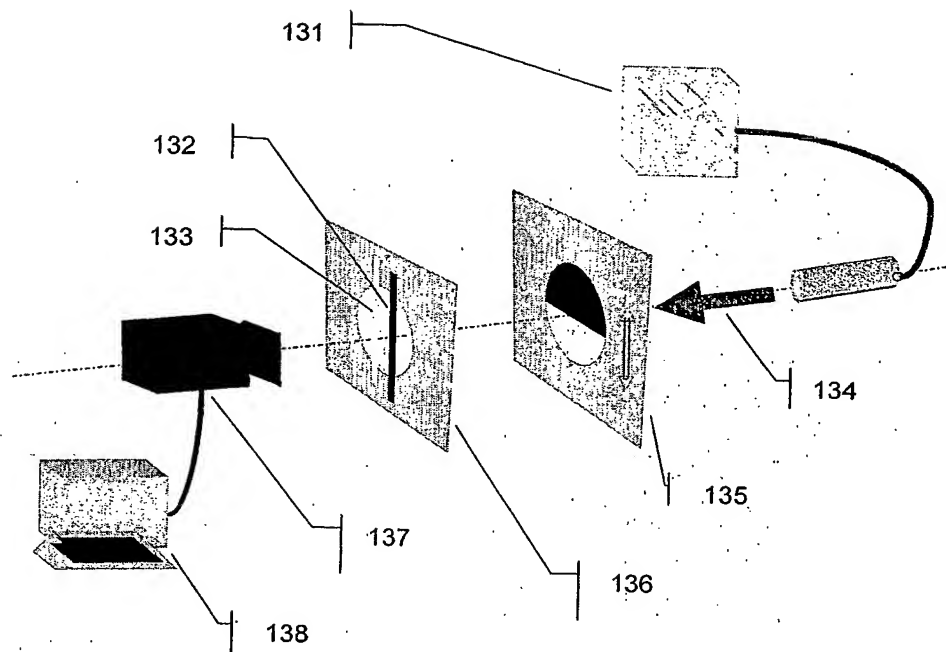
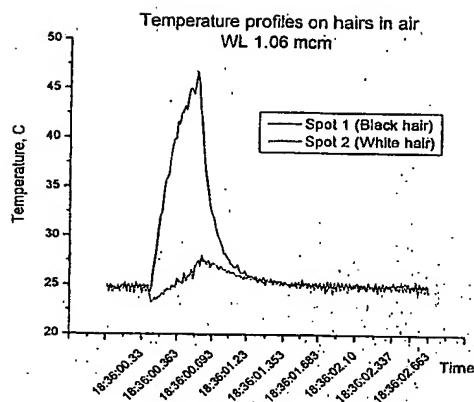
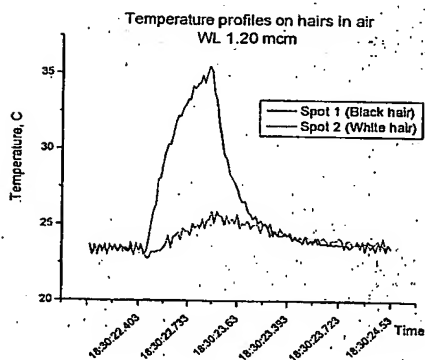


Figure 13

14 / 15



(a)



(b)

Figure 14

15 / 15

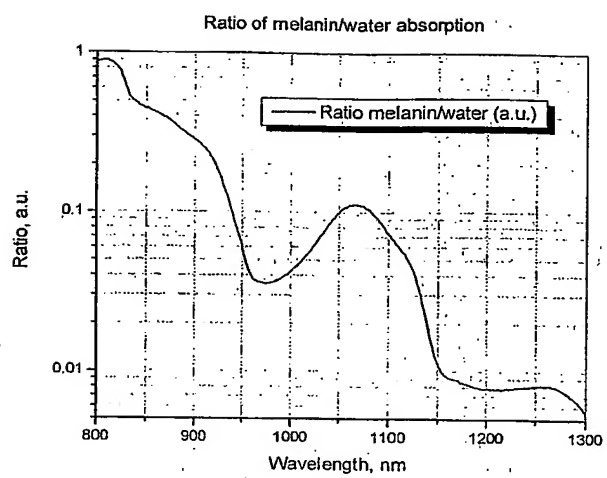


Figure 15

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
2 September 2004 (02.09.2004)

PCT

(10) International Publication Number
WO 2004/073537 A3

(51) International Patent Classification⁷: **A61B 18/20**

01887 (US). EROFEEV, Andrei, V. [RU/US]; 38 Royal Crest Drive #7 (US).

(21) International Application Number:
PCT/US2004/005174

(74) Agents: ENGELLENER, Thomas, J. et al.; Nutter McClennen & Fish LLP, World Trade Center West, 155 Seaport Boulevard, Boston, MA 02210-2604 (US).

(22) International Filing Date: 19 February 2004 (19.02.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/448,762 19 February 2003 (19.02.2003) US

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(71) Applicant (for all designated States except US): PALOMAR MEDICAL TECHNOLOGIES, INC. [US/US]; 82 Cambridge Street, Burlington, MA 01803 (US).

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

(72) Inventors; and

(75) Inventors/Applicants (for US only): YAROSLAVSKY, Ilya [RU/US]; 9214 Avalon Drive, Wilmington, MA 01887 (US). SMOTRICH, Michael [US/US]; 62 Sunset Rock Road, Andover, MA 01810 (US). ALTSHULER, Gregory, B. [US/US]; 137 Marion Street, Wilmington, MA

[Continued on next page]

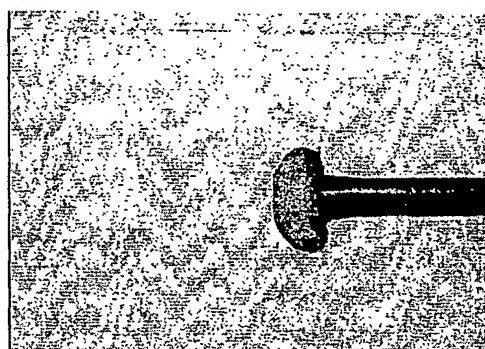
(54) Title: METHOD AND APPARATUS FOR TREATING PSEUDOFOLLICULITIS BARBAE

Before



(a)

After



(b)

(57) Abstract: Method and apparatus for hair treatment are disclosed which comprise applying electromagnetic radiation (EMR) to a skin treatment area to deposit energy in one or more hairs so as to modify a shape and/or chemical structure of at least a portion of the hairs. The applied radiation can cause heating of the hair tips, so as to modify their shape, e.g., reduce sharpness of the hair tips. Modification of the hair can involve heat-induced changes to the shape, composition, or function of the hair tip, hair shaft, and/or hair matrix that make the hair less capable of re-entering the skin. The methods and apparatus can treat and/or prevent pseudofolliculitis barbae (PFB) in the treatment area. A method is also disclosed for managing hair growth using wavelengths between 1200 nm and 1400 nm.

WO 2004/073537 A3



Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(88) Date of publication of the international search report:

2 December 2004

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/005174

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B18/20

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/023283 A1 (MCDANIEL DAVID H) 30 January 2003 (2003-01-30) paragraphs '0015!', '0052!', '0062! paragraph '0069!	1-6
X	US 2001/041886 A1 (DURKIN ANTHONY J ET AL) 15 November 2001 (2001-11-15) paragraph '0012! tables 1,3,4	1,3,5,6
Y		2,4
X	WO 99/49937 A (GEN HOSPITAL CORP ; PALOMAR MEDICAL TECHNOLOGIES I (US)) 7 October 1999 (1999-10-07) page 4, line 622 - page 5, line 2 page 7, line 6 - line 10	1,3,5,6
	----- -/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *G* document member of the same patent family

Date of the actual completion of the international search

14 September 2004

Date of mailing of the international search report

24.09.2004

Name and mailing address of the ISA
European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Lohmann, S

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US2004/005174

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 736 308 A (ESC MEDICAL SYSTEMS LTD) 9 October 1996 (1996-10-09) column 3, line 40 - column 4, line 19 -----	1,3,5,6
Y	WO 99/34867 A (AZAR ZION ; SHALEV PINCHAS (IL); DELIGHT TECHNOLOGIES LTD (IL)) 15 July 1999 (1999-07-15) page 10, line 1 - line 4 -----	2,4
X	WO 02/094116 A (ALTSHULER GREGORY B ; EFROFEEV ANDREI V (US); BURKE JAMES III (US); CA) 28 November 2002 (2002-11-28) page 30, line 21 - page 33, line 13 page 34, line 21 - page 35, line 12 page 38, line 16 - line 21 page 40, line 9 - line 13 page 41, line 18 figures 18A,18B,19,20,25 -----	1-9

Form PCT/ISA/210 (continuation of second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2004/005174

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 10-69
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (2)) (January 2004)

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 10-69

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US2004/005174

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 2003023283	A1	30-01-2003	US 2002123746 A1	05-09-2002
			US 6283956 B1	04-09-2001
			BR 0213996 A	31-08-2004
			CA 2465906 A1	15-05-2003
			EP 1453431 A2	08-09-2004
			WO 03039478 A2	15-05-2003
			US 2003004556 A1	02-01-2003
			AU 1746600 A	19-06-2000
			WO 0032121 A1	08-06-2000
			US 2003129154 A1	10-07-2003
			US 2003060811 A1	27-03-2003
US 2001041886	A1	15-11-2001	US 2003036749 A1	20-02-2003
WO 9949937	A	07-10-1999	AU 3363999 A	18-10-1999
			CA 2326120 A1	07-10-1999
			EP 1066086 A1	10-01-2001
			WO 9949937 A1	07-10-1999
			US 6605080 B1	12-08-2003
			US 2003199859 A1	23-10-2003
EP 0736308	A	09-10-1996	US 5683380 A	04-11-1997
			AU 717203 B2	23-03-2000
			AU 4817496 A	10-10-1996
			CA 2171260 A1	30-09-1996
			DE 29623504 U1	20-08-1998
			EP 0736308 A2	09-10-1996
			FI 961413 A	30-09-1996
			JP 8266326 A	15-10-1996
			US 6514243 B1	04-02-2003
			US 5885273 A	23-03-1999
			US 6280438 B1	28-08-2001
WO 9934867	A	15-07-1999	IL 122840 A	21-04-2002
			AT 235285 T	15-04-2003
			AU 743209 B2	24-01-2002
			AU 1504399 A	26-07-1999
			BR 9814562 A	17-10-2000
			CA 2316252 A1	15-07-1999
			CN 1283130 T	07-02-2001
			DE 69812716 D1	30-04-2003
			DE 69812716 T2	23-10-2003
			EA 2834 B1	31-10-2002
			EP 1232767 A2	21-08-2002
			EP 1232768 A2	21-08-2002
			EP 1058569 A1	13-12-2000
			ES 2190614 T3	01-08-2003
			HK 1033440 A1	15-08-2003
			WO 9934867 A1	15-07-1999
			JP 2002500080 T	08-01-2002
			US 6187001 B1	13-02-2001
WO 02094116	A	28-11-2002	US 2002128635 A1	12-09-2002
			CA 2448385 A1	28-11-2002
			EP 1401347 A1	31-03-2004
			WO 02094116 A1	28-11-2002
			US 2003032950 A1	13-02-2003
			US 2003195494 A1	16-10-2003

Form PCT/SA/210 (patent family annex) (January 2004)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US2004/005174

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 02094116	A	WO 03077783 A1	25-09-2003
		US 2004034319 A1	19-02-2004

Form PCT/ISA/210 (patent family annex) (January 2004)

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☒ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.

THIS PAGE BLANK (USPTO)